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Program Evaluation and Methodology Division

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The Honorable Henry Waxman Chairman, Subcommittee on Health and the Environment Committee on Energy and Commerce House of Representatives



Dear Mr. Chairman:

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As you requested, this report contains our additional descriptive analyses and profiles of two types of medical device recalls, based on the data we collected for our August 1989 report entitled Medical Device Recalls: An Overview and Analysis 1983-88 (GAO PEMD-89-15BR). In that report, we provided information on the overall numbers and selected characteristics of all recalls that were initiated during the 1983-88 study period. Appendix I of this report contains further background information and a description of our study's objectives, scope, and methodology.

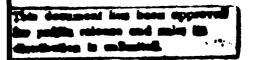
In appendices II and III, we have included the results of our further analyses of two types of recall: (1) those that involved medical devices approved for marketing by the Food and Drug Administration (FDA) through its premarket approval (PMA) process and recalled for some type of design problem (hereafter referred to as PMA-design recalls) and (2) those that FDA classified as the most serious according to health risk (class I).

Our medical device recall profiles include product and manufacturer identification, the nature of the problem for which the device was recalled, the health consequences of the device problem, and a description of the recall, (See appendices IV and V.)

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Results in Brief

In our additional analyses and profile development, we found that there were 28 pma-design and 48 class I recalls. Six recalls fell into both groups, and taken together, the two categories accounted for 70, or 4 percent, of the universe of recalls (1.635) initiated during fiscal years 1983 through 1988. Although they are a relatively small proportion of the total, these two types of recall are probably among the most important from a public health perspective. This is so because devices involved in pma-design recalls were determined to be unlike any other devices currently on the market or were assigned by FDA to the highest risk category (class 3) and then passed through FDA's most stringent



GAO PEMD-90-6 Examination of Selected Medical Device Recall Cases



review of evidence pertaining to their safety and effectiveness. And, class I recalls are reserved for those situations in which there is the greatest likelihood that the death of a patient or other serious adverse health consequence could occur because of a device problem.

The most frequent causes of PMA-design recalls were failure of the device to perform during use as reliably as expected and failure of the original process design to achieve its intended results. Design problems were also the most frequent reason for initiating class I recalls. There were no actual adverse health consequences associated with the majority of PMA-design recalls or with 42 percent of the class I recalls. However, about one third of the PMA-design recalls and over half the class I recalls were associated with at least one patient's injury or death. FDA's computerized recall data bases, which were the basis of this report, were not designed to store and aggregate all the available information about a particular recall. They do not include the total number of patient injuries and deaths associated with the product. Therefore, we could not determine whether the data entry indicating "at least one injury or death" was an accurate indicator of the overall adverse health consequences of these recalls.

There is no requirement that device manufacturers notify FDA of recalls, and we found that in many cases the agency was not aware of the recall until after it had started or even until it had been completed. FDA was notified of 42 percent of PMA-design recalls either after they had started or only after they had been completed. Similarly, the agency learned of many class I recalls (44 percent) after they had been initiated. In nearly half of the cases, FDA learned of both PMA-design and class I recalls from a source other than the manufacturer. The other sources included device users, competitors, and FDA inspections. FDA did not formally request that manufacturers initiate any of the recalls in this study; all were recorded as having been voluntarily initiated by manufacturers.

Additionally, we found that reports of device problems, as prescribed in the medical device reporting regulation, had not been filed on the devices involved in 64 percent of the PMA-design recalls or nearly half the class I recalls at the time of FDA's evaluation of the potential health hazard of the device problem and determination of the appropriate classification of the recall.

Issues for Future Study

The data contained in this report suggest the need for additional study in this area to focus on potential vulnerabilities in FDA's medical device premarketing approval and recall processes. The facts presented here lead to questions about the number of device recalls that remain unknown to FDA and about the timeliness of those recall actions taken by FDA and device manufacturers that originate in either biennial good manufacturing practices inspections or in the irregularly scheduled inspections conducted for other purposes. They also call into question the effectiveness of the medical device reporting (MDR) regulation as an "early warning" of medical device problems that may lead to recalls, given that nearly two thirds of PMA-design and almost half of the class I recalls did not have an MDR report associated with them when critical FDA decisions about the recall were being made.

It was beyond the scope of this study to review and assess the underlying structures, procedures, and overall operations of either the medical device premarket approval or recall system. Such an assessment would provide the broader context for viewing the recalls presented in this report and in our earlier briefing report. However, the nature and content of the data bases that were the source for this analysis permit only a descriptive overview of recalls.

A more complete understanding of the structure and processes involved in the medical device recall system and of the implications of its operation in particular cases could be gained by selecting a sample of recalls and reviewing them in depth, making use of FDA's detailed case history files and additional data collected from device manufacturers and users. We will examine such a sample of recalls in a subsequent study. A careful sample selection process in such a study could provide insights into how the recall process operates for various types of devices and thus a basis for interpreting the descriptive overview developed in this report.

As you requested, we obtained informal, ora——ments from FDA officials. Their comments were primarily technical, and we revised our draft to take account of them as appropriate. As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after the issue date. At that time, we will send copies to the secretary of Health and Human Services and the director of the Center for Devices and Radiological Health, and to other interested parties upon request.

¹Geoff's General Accounting Office, Medical Device Recalls. An Overview and Analysis 1983/88, GAO/PEMD-89-15Bit et al., chington, D.C.; August 1989.

If you have any questions or would like additional information, please call me at (202) 275-1854 or Dr. Michael J. Wargo, Director of Program Evaluation in Physical Systems Areas, at (202) 275-3092. Other major contributors to this report are listed in appendix VI.

Sincerely yours.

Eleanor Chelimsky

Assistant Comptroller General

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	Abbrevi	ations	. ==
	CDRH FDA GAO MDR	Center for Devices and Radiological Health Food and Drug Administration General Accounting Office Medical device reporting (regulation)	

Background, Objectives, Scope, and Methodology

Background

Each day thousands of individual medical devices are used in the diagnosis and treatment of illness and injury. The Food and Drug Adminis tration (FDA)—which is authorized to regulate medical devices during all phases of their development, testing, production, distribution, and use—recognizes more than 1.600 different types of medical devices. They represent an industry of more than \$14 billion in sales annually.

Recent decades have seen massive changes in the variety and complexity of medical devices; greater dependence on technology for most aspects of medical diagnosis, therapy, and care of the ill; and a phenomenal rise in automation. Radical treatments now involve plastic, metallic and electronic implants. Health care professionals must now choose among medical devices, many of which lack product standardization, become rapidly obsolete, or malfunction in ways that defy detection until a patient has been injured thereby.

FDA uses two principal systems to assure the safety and effectiveness of medical devices. The first, premarketing review, is a system of checks, reviews, and approval requirements that are applied before a device is made available to the public. The second, postmarketing surveillance, is a monitoring system designed to provide an "early warning" of problems associated with the devices after they are in general use. We examined the implementation of one element of the postmarketing surveillance system, the medical device reporting (MDR) regulation, in a previous report. The MDR regulation, which went into effect on December

¹The term "medical device" is defined in Section 201(h) of the Federal Food, Drug- and Cosmetic Act of 1938 (as amended by the Medical Device Amendments of 1976) as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is recognized in the official National Formulary or the U.S. Pharmacopeia or any supplement to them, that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or intended to affect the structure or any function of the human body or bodies of other animals, and that does not achieve any of its principal intended purposes through chemical action within or on the body and does not depend upon being metabolized in order to achieve any of its principal intended purposes. The effect of the 1976 amendments was to enlarge the 1938 definition to include devices intended for use in diagnosis of conditions other than diseases (such as pregnancy), in vitro diagnostic products, and specific products previously regulated as new drugs, including soft contact lenses bone cements, and sutures.

^{*}See U.S. General Accounting Office, Medical Devices. FDA's 510(k) Operations Could Be Improved. GAO PEMD-88-14. Washington D.C. August 1988) for a more detailed discussion of FDA's premarketing review system.

See U.S. General Accounting Office, Medical Devices, Early Warning of Problems is Hampered by Severe Underreporting, GAO, PEMD \$7,1. Washington, D.C. December 1986) for a more detailed discussion of FDA's postmarketing surveillance activities.

See U.S. General Accounting Office, Medical Devices. FDA's Implementation of the Medical Device Reporting Regulation, GAO, PEMD-89-10, Washington, D.C., February, 1989.

Appendix I Background, Objectives, Scope, and Methodology

13, 1984, requires that a problem report be submitted to FDA whenever manufacturers or importers of medical devices become aware of information that reasonably suggests that one of their devices may have caused or contributed to serious injury or death, or that the device has malfunctioned and, if the malfunction recurs, is likely to cause or contribute to a serious injury or death.

Medical device recalls constitute a second element of the postmarketing surveillance system. If a product exhibits a problem after it has been made available for general use, or if empirical data on postmarketing use (including MDR reports) indicate that a problem's rate of occurrence exceeds an expected range, one of the remedial actions available to the device's manufacturer is to recall the product or remove it from the market. FDA has no authority under the Federal Food, Drug, and Cosmetic Act, as amended, or any other laws it administers to order a manufacturer to recall a product without a court order, but the agency may request a recall. In practice, the overwhelming majority of recalls are voluntarily initiated by the manufacturer, with FDA oversight.

At the request of the chairman of the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, we conducted a review and analysis of those medical device recalls known to FDA that were initiated in fiscal years 1983 through 1988. The results of this review are contained in our report entitled Medical Device Recalls: An Overview and Analysis 1983-88 (GAO PEMD-89-15BR).

In response to this earlier report, the chairman requested that we provide the Subcommittee with a follow-up report containing additional information about two specific types of medical device recall: (1) recalls of devices approved for marketing through FDA's premarket approval (PMA) process but subsequently recalled because of design problems

In addition to employing the term "recall" to refer to the removal of a device from the market or its return to the manufacturer for repair, FDA also uses the word to denote field repairs. hazard warnings, the correction of labeling or promotional materials that the agency considers to be in violation of the laws it administers, and other situations.

^{*}See U.S. General Accounting Office Medical Device Recalls: An Overview and Analysis 1983-88 GAO PEMD-89 15BR · Washington, D.C. Angust 1989), for a more detailed discussion of FDA's recall related authority and further background information.

[&]quot;Because there is no statutory or regulatory requirement that manufacturers report recalls to FDA some corrective actions taken by manufacturers that would be classified as recalls by FDA may remain unknown to the agency, and consequently would not be included in the totals derived from FDA's records.

Appendix I Background, Objectives, Scope, and Methodology

(hereafter referred to as PMA-design recalls) and (2) class I (the most serious) recalls.

These two subsets of all the possible types of recalls were selected by the Subcommittee because of the characteristics of the pMA-design recalls and the seriousness of the potential health consequences associated with class I recalls. The statutory requirement for "well controlled investigations" or other "valid scientific evidence" of a device's safety and effectiveness is an integral part of the premarket approval process. It is therefore of special interest when a device with a premarket approval is recalled on account of a problem attributed to its design. Class I recalls are of interest because they are the most serious in FDA's three-level classification of recalls, a system based on the potential health and safety risks posed by the device problem.

During fiscal years 1983 through 1988, there were 28 recalls in the PMA-design category, and there were 48 class I recalls. Six of the 28 PMA-design recalls were judged by FDA to involve health risks serious enough to warrant classification as class I, so the two sets of recalls that are the subject of this report overlap to this extent. Together the two categories accounted for 70, or 4 percent, of the 1635 total recalls initiated from fiscal year 1983 through fiscal year 1988.

Objectives, Scope, and Methodology

For each PMA-design and class I recall, our principal objectives were

- to identify the recalled product and its manufacturer;
- to describe the nature of the problem for which the device was recalled:
- · to identify the health consequences of the device problem; and
- to provide a description of the recall (its date, magnitude, and other characteristics).

We have also provided statistical summaries of the two categories of recalls and discussed some possible implications of their characteristics.

[&]quot;Appendix II contains from or discussion of the premarket approvar process."

Design is one of mice are gories used by FDA analysis to classify the coasses of device provious adentified by manufacturers. So appendix II of this report and one can are report or those Mode at Device Rocalis. An Overview and Analysis 1983-88, pp. 22–23, for a getailed discussion of FDA's device problem causar attribution system.

See appendix III for an one detailed discussion of FDAs results l'essiticate non terra

Appendix I Background, Objectives, Scope, and Methodology

The information on which this report is based was derived from the integration of two automated data bases maintained at the Center for Devices and Radiological Health (CDRII). They are called the "recall" and "problem" data bases and were set up to track recall processing at CDRII. These data also permit analysis of the causes of device problems; however, they are not the primary recall records. FDX officials stated that the complete history of each recall is contained only in archived paper and microfiche files maintained by CDRII. A systematic review of these files was 1—youd the scope of this study. We will examine a sample of the records in a subsequent study.

FDA provided us with a computer tape that contained information on recalls initiated during fiscal years 1983 through 1988. We did not independently verify the information contained on the data tape or evaluate the internal controls of the computer systems that produced the tape. We did, however, examine extreme entries, deleted some that were logically impossible, and corrected a number of other data-entry errors in consultation with FDA staff. For example, we found a number of cases in which important information about the recall (such as whether an injury or death had occurred) was missing from the tape. And, in some other cases, the stored data were contradictory or unclear. (For example, in one case, a parrative data field indicated that "numerous deaths" had been reported, but the data field for health consequences contained the code for "at least one patient injury.") When CDRH analysts were able to provide documentation of the data-entry errors, we corrected the information on the data tape.

Our analysis was conducted during the months of June and July 1989, using the frequency and cross-tabulation procedures of the Statistical Analysis System, and was performed in accordance with generally accepted government auditing standards.

¹³The data tape that FDA provided to us contained records for 4° recalls that fell into the PMA design category. Powever, as this report was being prepared for publication, CDRH staff discovered systematic errors in one of their data bases. Thereen recalls were found not to have involved a premarket approved device as the data base had indicated. Our correction of these errors reduced the PMA design category to 28 recalls.

The Premarket Approval Process

Premarket approval (PMA) of a device is required in order to market a medical device when the general controls authorized by the Federal Food, Drug, and Cosmetic Act, as amended, are insufficient to ensure safety and effectiveness, when information does not exist to establish a performance standard, and when the device supports life, prevents health impairment, or potentially presents an unreasonable risk of illness or injury. Premarket-approved devices include complex drug-delivery systems, life-supporting prostheses, and sophisticated electronic devices for controlling, modifying, and performing essential physiological functions. PMA is granted on the basis of "well controlled investigations" or other "valid scientific evidence" that supports the device manufacturer's or importer's claim that its device is safe and effective.

In a related study, we reported that available statistics on original PMA applications and approvals showed that over the past seven years, PMA applications have ranged between 60 and 97 per year and approvals between 24 and 72 per year. A total of 323 applications were approved between 1976 and 1986. In addition, FDA received almost 2,400 PMA application "supplements" between 1980 and 1986, and roughly 1,900 (79 percent) of these were approved. Although PMA devices represent a relatively small proportion of the medical devices entering the market-place, PMA devices have special importance because they have passed through what is intended to be FDA's most stringent review of evidence pertaining to the device's safety and effectiveness. Thus, when one of these devices must be recalled for a problem attributed to its design, that recall may have important implications for the PMA process.

FDA's review of PMA applications has three major steps: (1) administrative review to determine whether the application includes all the required information and is otherwise suitable for filing. (2) scientific

³See U.S. General Accounting Office, Medical Devices, FDA's 540ck (Operations Could be Improved, GAO/PEMD 88-14) (Washington, D.C.; August 1988), pp. 35-39, for a more detailed discussion of the premarket approval process.

Since 1976, premarket notification as prescribed in section 510(k) of the amendments has been the predominant route to commercial distribution for medical devices. Section 510(k) of the amendments requires that device manufacturers (1) notify FDA at least ninety days before marketing a new device, (2) provide their preliminary judgment concerning the class that the device belongs meand the basis for that assessment, and (3) describe the actions they have taken to comply with the applicable performance standards (section 514) or premarket approval (section 515) provisions of the amendments. Section 510(k) does not explicitly require FDA to review the manufacturer's indignant concerning classification of the device. Nor does it require the manufacturer to retrain from marketing for more than 90 days if FDA has not made a determination. In our earlier study envited Medicai Devices. FDA's 510(k) Operations Could Be Improved, pp. 22-23, we reported that during the previous seven years there was an average of 5,000-510(k) or premarket notification applications amonally, with an 85 percent approval rate.

and regulatory review by scientific and compliance personnel, and (3) review and recommendation by an advisory committee composed of experts from the medical and other relevant academic fields.

The administrative review is the "gatekeeper" that assures FDV of having a complete application before the device is put through the scientific and regulatory review of the manufacturer's claim that the device is safe and effective. For this latter step, the regulations set forth standards of scientific evidence that the agency must apply. The review may be based on controlled studies and investigations, objective trials without matched controls, documented case histories conducted by qualified experts, reports of significant experience (such as the results of research conducted in foreign countries), or any combination of these forms of evidence.

For devices that have been approved for marketing through this route and are later changed or made to deviate from the conditions described in the original approval, manufacturers must obtain FDX's approval of a "supplemental" premarket application describing the changes and showing that the changed device remains safe and effective. Supplements are required for, among other things, adding a new indication for use, using a new principle of operation, and adding a color additive that comes in contact with the body for a significant period of time.

In spite of the requirements of the premarketing notification and approval processes, it is impossible to identify and solve all of the potential problems that a device may experience once it is in general use, and some of the problems that occur while a device is in use lead to a decision to recall the product. Based on the experience of FDV's Center for Devices and Radiological Health (CDRH) analysts. FDX developed a ninecategory scheme for the common causes of device problems that lead to recalls. These include: (1) design, (2) production control, (3) component control, (4) expiration dating and Radiation Control for Health and Safety Act violations, (5) change control, (6) training, (7) unsbranding, (8) no premarket approval, and (9) other. Most recalls are assigned to one of the classes by CDRH analysts after reviewing narrative statements, provided by the manufacturer, about the cause of the device problem.

See Medical Device Recalls. An Overview and Analysis 1980-88, GAO, PEMD 89 USBR, Washington D.C., August 19895, pp. 22–23, for a detailed definition and discussion of other cause's bases and examples of each

In our earlier analysis of recalls, we found that a problem with product design was the most frequent overall cause of medical device recalls, accounting for 44 percent of the 1,635 recalls that occurred between fiscal years 1983 and 1988. FDA further divided the "design" category as a cause of device problems into seven subcategories. These subcategories are shown in table II.1.

 $^{^4 \}mathrm{See}$ Medical Device Recalls, An Overview and Analysis 1983-1988, pp. 23-24

FDA officials said that they do not regard all seven of the subcategories as referring to kinds of problems that might reasonably be expected to be prevented by the premarket approval process. They identified categories D1, D2, and D5 (labeled respectively "device design," "component design selection," and "software design" as most relevant to the PMA process.

Code	Category	Definition	Examples
D1	Device design	The finished device does not perform as reliably as expected during use although it meets the approved original design specifications is not adversely affected by the manufacturing process or use of a defective component or material, and is properly used according to its labeling.	(1) Tubal occlusion clips repeatedly fell off the clip applicator into the patient due to poor design of the applicator head. (2) the physical location of a ventilator switch resulted in the ventilator being accidentally shut off, and (3) the coating on slides in a test kit peeled due to humidity.
D2	Component design/selection	Components, materials selected designed for an application do not perform as reliably as expected although they meet the original or modified specification and are not adversely affected by the manufacturing process	(1) The plastic raw material used in a female luer lock did not have sufficient strength and cracked under use (2) a preservative used in an in vitro diagnostic broke down when subjected to righ temperature, diluting the diagnostic medium, and (3) a flexible rubber component used in a preset magnetic valve allowed the magnets to shift, resulting in preset condition change.
D3	Packaging design/selection	The packaging does not properly serve its intended function although it is manufactured as designed and is not adversely affected by the manufacturing process	(1) Packaging for a sterile device could not be adequately sealed because of the adhesive composition (2) a test kit was adversely affected during shipment due to freezing because it was not adequately protected against warehouse conditions, and (3) the outer wrapper of condoms allowed the lubricant to dry out
D4	Labeling design	Labeling does not contain information required by labeling regulations (21 CFR 801 & 21 CFR 809.10)	Labeling was unacceptable because it lacked name and address of manufacturer and other required information was missing
D5	Software design (device) including firmware	The software does not adequately perform its intended function although the program is written and prepared as designed	(1) Pacemaker programmer allowed pacemaker to be programmed into an incorrect configuration (2) the algorithm did not accurately convert pressure signal to readings at low pressures
⊃6	Software design (manufacturing process)	The original process software does not adequately perform its intended function although the program is written prepared and implemented as designed.	Lack of software validation led to labeling of contact lenses with incorrect expiration dates
D7	Process design	Implementation of the original process design does not achieve its intended results adversely affecting the product or resulting in conditions that could have an adverse effect on health	(1) Lack of packaging controls to assure sealed device compromised sterility of a urethral catheter. (2) inadequate welding procedures validation, and stress testing led to strut failures of heart valves.

Source CDPH FDA Problem Jailse Solution Clode Director,

Descriptive Analysis

Between fiscal years 1983 and 1988, there was a total of 28 medical device recalls involving devices that had entered the market via FDA's PMA process and were subsequently recalled because of a design problem (PMA-design recalls). For example, a manufacturer obtained a PMA for a heart valve and later received information suggesting that something about the design of the valve might be causing it to fracture after it had been implanted. When the manufacturer recalled the valve, this constituted a PMA-design recall. These types of recall represent approximately 2 percent of all the device recalls that FDA learned of during those years. This appendix contains a summary of information about premarket-approved medical devices recalled because of design problems. Appendix IV presents a case-by-case profile of this information.

Fiscal year 1987 saw the largest number of PMA-design recalls, 8, which were 29 percent of the total number of such recalls during the years 1983-88. Table II.2 shows the complete distribution of PMA-design recalls over these fiscal years.

Table II.2: PMA-Design Recalls, Fiscal Years 1983-88

Fiscal year	No. of recalls	Percent
1983	4	14%
1984	2	7
1985	6	21
1986	5	18
1987	8	29
1988	3	11
Total	28	100%

Source FDA recall data tape

The majority of PMA-design recalls (18, or 64 percent) were designated by FDA as class II (medium serious). Of the remaining 10 recalls, 6 were class I (most serious) and 4 were class III (least serious), as indicated in table II.3.

^{&#}x27;See appendix III for a detailed explanation of the three recall classes.

Table II.3: PMA-Design Recalls by Recall Class, Fiscal Years 1983-88

Recall class	No. of recalls	Percent ^a
I (most serious)	6	21° _n
II (medium serious)	18	64
III (least serious)	4	14
Total	28	100%

'Percentages do not total 100 because of rounding Source FDA recall data tape

Two of FDA's three device classes were represented among the PMA-design recalls. As would be expected, because all class 3 (high-risk) devices require premarket approval, most PMA-design recalls (25, or 89 percent) were associated with class 3 devices. As indicated in table II.4, class 2 devices were associated with 3, or 11 percent, of the recalls.

Table II.4: PMA-Design Recalls by Device Class, Fiscal Years 1983-88

Device class	No. of recalls	Percent
2 (medium risk)	3	11°0
3 (high risk)	25	89
Total	28	100%

Source FDA recall data tape

Eight of the 19 medical specialties used by FDA in device classification were represented among PMA-design recalls. Devices falling within the cardiovascular-specialty classification were the type of device most frequently involved in PMA-design recalls, with 11, or 39 percent. As table II.5 shows, devices falling within the ophthalmology specialty accounted for 6, or 21 percent; the anesthesiology and gastroenterology, urology specialties followed, with each accounting for 3, or 11 percent, of the recalls. No other medical specialty accounted for more than 7 percent of the PMA-design recalls.

The 1976 Amendments created a three-tiered system in which devices would be classified and regulated by FDA according to their potential health risk, with class 1 devices presenting the least risk and class 3 devices the most. It is important to remember that the potential degree of health risk associated with recall classes is designated in a descending order from class 1 to class III, and the risk of device classes is designated in an ascending order from class 1 to class 3. Therefore, classes 1 and 1 have opposite meanings for recall and device classes. See Medical Device Recalls: An Overview and Analysis 1983-88, p. 15, for a more detailed explanation of the criteria for device classification and appendix III of this report for a discussion of recall classification.

⁸FDA's 19 medical specialties are anesthesiology, cardiovascular, chemistry, dental, car, nose, and throat; gastroenterology and urology; general hospital; general and plastic surgery; hematology, immunology; microbiology; neurology; obstetries and gynecology, ophthalmology; orthopedic; pathology; physical medicine; radiology; and toxicology

Table II.5: PMA-Design Recalls by Medical Specialty, Fiscal Years 1983-88

Medical specialty	No. of recalls	Percent ^a
Cardiovascular	11	39%
Ophthalmology	6	21
Anesthesiology	3	11
Gastroenterology, urology	3	11
General and plastic surgery	2	7
Immunology	1	4
Neurology	1	4
Orthopedics	1	4
Total	28	100%

"Percentages do not total 100 because of rounding Source_FDA recall data tape."

As indicated in table II.6, there were two subcategories of design problem that most often resulted in a PMA-design recall. In the first, some element of a device's design caused the finished device not to perform as reliably as intended. This type of design problem accounted for 8, or 29 percent, of the PMA-design recalls. In the second—which also accounted for 8, or 29 percent, of the PMA-design recalls—the implementation of the original process design did not achieve its intended results. In addition, faulty component design or selection was responsible for 6, or 21 percent, of the recalls. Finally, there were three PMA-design recalls in which a device's software did not perform its intended function adequately—even though the program was written, prepared, and implemented as designed.

Table II.6 PMA-Design Recalls by Specific Design Problem Categories, Fiscal Years 1983-88

Category	No. of recalls	Percent ^a
Device design	8	29%
Process design	8	29
Component design/ selection	6	21
Software design (device)	3	11
Fackaging design/ selection	1	4
Labeling design	1	4
Software design (manufacturing)	1	4
Total	28	100%

"Percentages do not total 100 because of rounding Source FDA recall data tape."

As the data in table II.7 indicate, FDA was notified or became aware of PMA-design recalls prior to their initiation in 11 cases, or 58 percent of the time. In the remainder of the cases, FDA learned of the recalls after they had started or were already over. In over half the cases (57 percent), FDA learned of the existence of the recall from the device manufacturer. (See table II.8.) However, in nearly one third of the cases, FDA discovered the recall or was informed that it would take place during one of its inspections of a manufacturer—for example, during one of its biennial good manufacturing practices or MDR inspections. In the remaining cases, FDA was notified of the recall by a device user or a competitor. The competition of the recall by a device user or a competition.

Table II.7: When FDA Learned About PMA-Design Recalls, Fiscal Years 1983-88

When FDA learned about recall	No. of recalls ^a	Percent ^b
Before recall	11	58%
During recall	6	32
After recall	2	11
Total	19	100%

*Data were missing in 9, or 32 percent, of the 28 PMA design recall cases

Source FDA recall data tape

Table II.8: How FDA Learned of PMA-Design Recalls, Fiscal Years 1983-88

How FDA learned of recall	No. of recalls ^a	Percent ^b
Notified by firm	12	57%
FDA inspection	16	29
Notified by user	2	10
Notified by competitor	1	5
Total	21	100%

Data on how FDA learned of a recall were missing or listed as N(A) in 7 or 25 percent of the 28 PMA design recall cases

Source: FDA recall data tape

 $^{^3}$ These percentages are based on the 19 recalls for which data were present. Percentages do not total 100 because of rounding

These percentages are based on the 21 recalls in which the source of notification was indicated. Percentages do not total 100 because of rounding.

Data on when FDA was notified or became aware of PMA design recalls were missing in 9 cases. These percentages are based on the 19 cases for which data were present.

 $^{^{10}\}mathrm{Data}$ on how FDA learned of a recall were missing or listed as "N/A" in 7, or 25 percent, of the 28 PMA-design recall cases. These percentages are based on the 24 recalls in which the source of notification was indicated.

Manufacturers are not required by statute to notify FDA about recalls, but the reporting requirements of the MDR regulation appear to require MDR reports on events that are serious enough to warrant any class I and at least some class II recalls. MDR did not, however, appear to serve FDA as a very effective "early warning" of the device problems leading to PMA-design recalls. Sixty-four percent of the PMA-design recalls initiated during the years since the MDR regulation went into effect did not have an MDR report associated with them at the time that FDA evaluated the health hazard of the device problem prompting the recall. (See table II.9.)

Table II.9: PMA-Design Recalls With and Without MDR Reports, Fiscal Years 1985-88

No. of MDR reports	No. of recalls ^a	Percent
At least one	8	36°。
None	14	64
Total	22	100%

⁴MDR report data were missing in 6, or 22 percent, of the 28 PMA-design recall cases. Source, FDA recall data tape.

The data in table II.10 show that there were no adverse health consequences associated with the majority (19, or 68 percent) of the PMA-design recalls. The four PMA-design recalls that were associated with the death of a patient all involved replacement heart valves. Five of the 28 recalls (18 percent) were associated with a patient injury.

Table II.10: Adverse Health Consequences Associated With PMADesign Recalls, Fiscal Years 1983-88

Reported health consequence	No. of recalls	Percent
Patient death	4	14°°
Patient injury	5	18
No deaths or injuries reported	19	68
Total	28	100%

Source FDA recall data tape

¹¹See our report entitled Medical Devices, FDA's Implementation of the Medical Device Reporting Regulation, GAO PEMD 89-10 (Washington, D.C., February 1989), pp. 14-15, for a detailed explanation of the reporting requirements.

Descriptive Analysis of Class I Medical Device Recalls

Introduction

FDA has established three regulatory classes of recalls; class I, class II, and class III. Our focus in this appendix is the class I recall. The basis for a class I recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (as when, for example, an implantable cardiac pacemaker is recalled because its batteries are failing prematurely).

This class of recall is labeled "most serious," in contrast to the situation in class II where FDA has determined that the use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences or that the probability of serious health consequences is remote, and in contrast to class III, where the use of, or exposure to, the product is not believed likely to cause adverse health consequences.

This appendix presents the relevant findings from our earlier report that were related to class I medical device recalls. It also contains additional descriptive analysis of the class I recalls included in the case-by-case profiles presented in appendix V.

Descriptive Analysis

In our earlier study of medical device recalls, we determined that FDA learned of a total of 1,635 recalls from fiscal year 1983 through fiscal year 1988. Of that total, 48 (or 3 percent) were class I recalls. Class I recalls occurred in eight of FDA's 19 medical practice specialties. As expected, we found that devices with highest risks for a patient injury (that is, class 3 devices) were more likely to be among the most serious recalls (that is, class I), while devices with the lowest risk (that is, class I) were more likely to be included among the least serious class of recalls (that is, class III). However, nearly two-thirds of class I recalls (65 percent) were associated with medium-risk class 2 devices—that is,

⁵21 CFR 7/3 Sec Federal Register, 43 June 16, 1978, p. 26/18

See U.S. General Accounting Office, Medical Device Recalls. An Overview and Analysis 1983-1988, GAO PEMD 89-15BR (Washington, D.C., August 1989), pp. 45-17.

See Medical Device Recalls: An Overview and Analysis 1983-1988, p. 12

those which require performance standards to ensure their safety and effectiveness.⁴

There was a positive relationship between the recall class and the existence of an MDR report—that is, the more serious the level of the recall. the more likely it was that an MDR report was associated with the device problem. Nonetheless, only 16, or 52 percent, of the class I recalls had a report associated with them at the time FDA evaluated the health hazard posed by the device problem which prompted the recall. Generally, devices that entered the market through the PMA process were more likely to be associated with a class I recall than with either of the two other classes of recall. In contrast, recalls of devices without PMAS were most often placed in class II. This tendency of PMA-device recalls to be placed in class I is not surprising, because some of the same factors that led to the requirement for premarket approval of a device would also be likely to cause its recall to be placed in class I. These factors include consideration of whether the device is either a life-supporting prosthesis or a complex, sophisticated electronic device used in controlling, modifying, or performing essential physiological functions.

A further analysis of the data indicated that the majority of these recalls (29, or 60 percent) occurred because of some type of design problem. (See table III.1.) Problems involving production controls—that is, the execution of the manufacturing plan or the actual implementation of equipment and procedures—accounted for 19 percent of these recalls. Problems with component controls—that is, the use of nonconforming or contaminated components in the manufacturing process—resulted in 5, or 10 percent, of the class I recalls.

The a previous study, we reported that no performance standards had yet been developed under the procedures detailed in the 1976 Amendments and that the tailure to develop such performance standards resulted in medium risk devices under premarketing review being treated in the same manner as the relatively uniocitous low risk devices. We note that the development of such standards would not necessarily have prevented the devices from being recalled. See U.S. General Accounting Office. Medical Devices, FDAS 510(k) Operations Could Be Improved, GAO, PEMD 88-14, Washington, D.C. August 1988), pp. 32-34.

Table III.1: Causes of Problems Leading to Class I Medical Device Recalls, Fiscal Years 1983-88

Category	No. of recalls	Percent ^a
Design	29	601s
Production control	Co.	∙ ુ
Component control	5	19
Change control		
Employee coror	1	2
No PMA	•	2
Other	•	2
Total	48	100%

Percentagis, in not hitter 100 because of rounding. Source IEDA recall data tabe.

As in the PMA-design recall situation, FDA became aware of the class I recalls before they were initiated in more than half the cases. (See table III.2.) The agency learned of 18, or 44 percent, of the class I recalls after they had started. However, in contrast to the PMA-design recall situation, FDA learned about all of the class I recalls before they had been completed.

Table III.2: When FDA Learned About Class I Recalls, Fiscal Years 1983-88

When FDA learned about recall	No. of recalls ^a	Percent ^b
Before recal	<u></u>	fici -
During recal-	• 🚊	4.4
After reca-		*
Total	41	100°。

Information on the tenings ODA's not to at an war movember T on to present of the 4π (4π) (4π) (4π)

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Because FDA's inspections of device manufacturers during the six years of our study period did not uncover any completed recalls serious enough to be placed in class Lit might be argued that few of these most serious recalls are likely to have remained unknown to FDA. There is, however, no statutory requirement that device manufacturers notify FDA of recalls, and some corrective actions by manufacturers serious enough to be labeled class I recalls did remain unknown to FDA until it learned of them during an inspection or was informed of them by a

Inform dron on the timing of FDVs notification was missing in $\mathbb N$ or 15 percent of the 48 class three mississ. These percentages are based on the 41 cases for which the data were according

device user or one of the manufacturer's competitors. As shown in table III.3, FDA was notified of class I recalls by the manufacturer in 23, or 58 percent of the cases, which is similar to the percentage of PMA-design recalls where FDA was informed by the manufacturer. In 17, or 43 percent, of the cases, FDA learned of the recall from some other source. In 10 of these cases, or 25 percent of the class I recalls, FDA learned of the recall through an agency inspection.

Table III.3: How FDA Learned About Class I Recalls, Fiscal Years 1983-88

	· - · · · · · · · · · · · · · · · · · ·	
How FDA learned about recall	No. of recalls ^a	Percent
Notified by firm	23	58°°
FDA inspection	10	25
Notified by user	6	15
Notified by competitor	1	3
Total	40	100%

Separation of the control of the state λ as massing or Stephas λ A in B or 17 per, ent of the 48 λ as in records

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The proportion of class I recalls that involved the occurrence of an adverse health consequence (that is, the injury or death of a patient) was greater than that for PMA-design recalls. (See table III.4.) This outcome was to be expected since PMA-design recalls are dispersed among all three recall classes, whereas only class I recalls are based on "a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." At least one death was associated with 17, or 35 percent, of the 48 class I recalls: 11, or 23 percent of these recalls, were associated with at least one injury. In the 20 cases that did not involve an injury or death, the potential for such adverse health consequences was nevertheless present in view of the fact that these cases were classified as class I recalls.

The source was 0.88 and classed as N(V) in S on 17 percent of the 48 class from a leases. These percentages are trased on the free lass from all sites which the source of the recall notation than understood.

Table III.4: Adverse Health Consequences Associated With Class I Recalls, Fiscal Years 1983-88

Reported health consequence	No. of recalls	Percent
Patient injury	11	23%
Patient death	17	35
No deaths or injuries reported	20	42
Total	48	100%

Source FDA recall data tape

Case number: 1 Product Identification Description: Vena cava occluder Device class: Medical specialty: Cardiovascular Brand: Occludes the vena cava, to prevent passage of thromboemboli Manufacturer: Concept, Inc., Clearwater, FL Problem Description: Blocked venogram port prohibited entry of X-ray dye Cause: Incomplete drilling of handle during manufacture (D7) a Health consequences: No deaths or injuries reported Recall Description Date: 12/14/82 Recall class: III Quantity recalled (units): 147 units Who notified FDA of recall?: When FDA learned of recall: During recall MDR report?: No FDA control number: 00373 Case number: 2 Product Identification Description: Transcutaneous gas monitor Device class: Medical specialty: Anesthesiology Brand: Use: Monitors gases in newborns Manufacturer: Novametrix Medical Systems, Wallingtord, CT Problem Description: Electrodes overheat, causing burns to skin Cause: Corrosion of electrical contacts in thermistor circuitry (D2) Health consequences: Patient injury Recall Description

Recall beautip Ton

Date: 11/15/82
Recall class: II
Quantity recalled (units): 1,443 units
Who notified FDA of recall: User
When FDA learned of recall: During recall
MDR report?: No
FDA control number: 20504

^{*}Missing or not clearly indicated on the FDA recall data tape.

Case number: 3

Product Identification

Description: Replacement heart valve Device class:

Medical specialty: Cardiovascular

Brand:

Replaces natural or prosthetic heart valve Use:

Shiley, Inc., Irvine, CA Manutacturer:

Problem

Description: Strut failure

Inadequate welding, validation, and stress Cause:

testing procedures (D7)

Health consequences: Patient death

Recall Description

Date: 06/06/83 Recall class: Quantity recalled (units): 5,770 valves Who notified FDA of recall?: Firm

When FDA learned of recall: During recall

MDR report?: FDA control number: 01523

Case number: 4

Product Identification

Description Test kit Device class: Medical specialty: Immunology

Brand: Quantitope AFP Test Kit Use: Used as a control

Manufacturer: Kallestad Labs, Chaska, MN

Problem

Description: Misbranded

Cause: Product distributed with a label which said

"FDA approved" (D4)

Health consequences: No deaths or injuries reported

Recall Description

07/07/83 Date: Recall class: III Quantity recalled (units): 150 kits Who notified FDA of recall?: Firm

When FDA learned of recall: MDR report?: บายยง FDA control number:

Case number: 5

Product Identification

Description: Replacement aortic valve

Device class:

Medical specialty: Cardiovascular

Bjork-Shiley Convexo-Concave 60-Degree Cardiac Brand:

Valve Prosthesis

Replaces natural or prosthetic heart valve Use:

Manufacturer: Shiley, Inc., Irvine, CA

Problem

Description: Strut failure

Inadequate welding, validation, and stress Cause:

testing procedures (D7)

Health consequences: Patient death

Recall Description

07/06/83 Date: Recall class:

7,400 valves Quantity recalled (units):

Who notified FDA of recall?: Firm When FDA learned of recall:

MDR report?: No FDA control number: 112 183

Case number: 6

Product Identification

Absorbable mesh for surgical use Description:

Device class:

Medical specialty: General and plastic surgery

Brand: Vicryl

Clamps blood vessels closed during surgery Use:

Manutacturer: Ethicon, Inc., Somerville, NJ

Problem

Possible non-sterility Description:

Product was stored in desiccant paper for a Cause: prolonged period before sterilization,

resulting in loss of moiscure (D/)

No deaths or injuries reported Health consequences:

Recall Description

11/07/83 Date:

1 I Recall class: 682 Quantity recalled (units):

Who notified FDA of recall?: Firm

When FDA learned of recall: During recall

MDR report?: No

20174 FDA control number:

Case number:

Product Identification

Description: Device class:

Medical specialty:

Brand: Use:

Manufacturer:

Implantable cardiac pacemaker

Cardiovascular

Regulates cardiac rate and rhythm

Cordis Corp., Mlami, FL

Problem

Description:

Cause:

Early battery failure

Pacemakers stressed by leing subjected to temperatures above 115 degrees C. during gas

analysis for moisture content; written quality control test inadequate and not

validated (D7)

192 pacemakers

Before recall

10/04/84

ΙI

Health consequences:

No deaths or injuries reported

Recall Description

Date:

Recall class:

Quantity recalled (units): Who notified FDA of recall?: FDA inspection

When FDA learned of recall: MDR report?:

FDA control number: *************

No 20595

Case number: 8

Product Identification

Description: Device class:

Medical specialty:

Brand: Use:

Manufacturer:

External cardiac pacemaker

Cardiovascular

Cordis Brand Chronscor III High-rate atrial pacing Cordis Corp., Miami, FL

Problem

Cause:

Description:

Switch intermittently shorts components, resulting in pacing rate 5 times the

programmed rate

Components selected and their arrangement were inadequate for the device's design (D1)

Health consequences: No deaths or injuries reported

Recall Description

Date:

Recall class:

Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall: MDR report?:

FDA control number:

06/11/85

ΙI 4 pacemakers FDA inspection During recall

No

25755

Case number: 9

Product Identification

Description: Device class:

Medical specialty:

Brand:

use:

Manufacturer:

Anesthesiology

Microprocessor analyzer

Microprocessor Based Analyzer

Lead testing of implantable passmaker

Seamed Corporation, Redmond, WA

Problem

Description:

Cause:

Inaccurate test results if used when the batteries were low or depleting

The low-battery warning scheme in the software

did not provide sufficient warning of

battery depletion (D5)

No deaths or injuries reported

Health consequences: Recall Description

Date: Recall class:

Quantity recalled (units):

Who notified FDA of recall?: FDA inspection When FDA learned of recall:

MDR report?: FDA control number:

Case number: 10

Product Identification

Description:

Device class: Medical specialty:

Brand:

Use:

Manufacturer:

Accessories to contact lenses

Ophthalmology

05/07/85

ΙI 57 units

No

23605

Aqua Pure, CVS, Brooks

Sterilization of contact lenses Sadler Wells, Inc., Lackawanna, NY

Problem

Cause:

Description:

Product was not packaged under aseptic conditions or in accordance with good

manufacturing practices

Firm was unaware that the product is a medical

device and tailed to obtain PMA or manufacture according to good

Health consequences:

manufacturing practices (D/) No deaths or injuries reported

Recall Description

Date: Recall class:

Quantity recalled (units): Who notified FDA of recall?: Competitor When FDA learned of recall:

MDR report?: FDA control number:

04/05/85 ΙI

1,500 cases During recall

No 23485

Case number: 11

Product Identification

Description: Device class:

Medical specialty:

Brand:

Use:

Manufact mor:

Plasma separator module

Gastroenterology, urology

Fenwal PS-400 Plasma Separator Model

Separation of plasma

Travenol Labs, Inc., Savago, MD

Problem

Cause:

Description:

Inaccurate scale readouts may result in

patient fluid imbalance

Voltage drop that may occur on the 5-volt DC supply to the scale circuitry, which is

aggravated if the 5-volt regulator is at the low end of its tolerance specification (D1)

No deaths or injuries reported

Health consequences:

Recall Description

Date:

Recall class: Quantity recalled (units): Who notif ed FDA of recall?:

When FDA learned of recall:

MDR report?: FDA control number: Before recall No

05/09/85

ΙI

28

Firm

23615

Case number: 12

Product Identification

Description:

Device class: Medical specialty:

Brand:

Use:

Manufacturer:

Contact lens accessories (distilled water)

Ophthalmology

Maintenance of contact lenses

Albany Laboratories, Inc., Albany, WY

Problem

Cause:

Description:

Product was contaminated with pseudomonas aeruginosa, an ophthalmic pathogen No PMA; product produced without good manufacturing practices (D7)

No deaths or injuries reported

Health consequences:

Recall Description

Date:

Recall class: Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall: MDR report?:

FDA control number:

08/20/85 11

No 25215

Case number: 13

Product Identification

Description: Replacement heart valve

Device class:

Medical specialty: Cardiovascular

Brand: Bjork-Shiley Cardiac Valve Prosthesis 600

(Mitral and Anrtic)

Use: Replaces natural or prosthetic heart valve

Manufacturer: Shiley, Inc., Irvine, CA

Problem

Description: Strut of the valves may fracture

Firm developed larger valves, having had Cause:

minimal failure with small valves; strut

failures began shortly after (D1)

Health consequences: Patient death

Recall Description

10/14/85

Recall class:

Quantity recalled (units): 2,752 valves

Who notified FDA of recall?: Firm

When FDA learned of recall: Before recall

MDR report?: Yes

FDA control number: Z1536

Case number: 14

Product Identification

Description: Cardiac pulse generator

Device class:

Medical specialty: Cardiovascular Brand: Programmalith III

Use: Regulates cardiac rate and rhythm

Manufacturer: Pacesetter Systems, Inc., Sylmar, CA

Problem

Description: Loss of function and telemetry capability due

to temperature sensitivity of circuits

Cause: Combination of resistance and amplifier gain in oscillator creates abnormal sensitivity

to temperature

Health consequences: Patient injury

Recall Description

Date: 09/04/85

Recall class:

Quantity recalled (units): 690 pacemakers Who notified FDA of recall?: Firm When FDA learned of recall: Before recall

MDR report?: No

21246 FDA control number:

Case number: 15

Product Identification

Patient monitor: arrythmia detector and alarm Description:

Device class:

Medical specialty: Cardiovascular

Brand: H-P Adult Monitors, Models /8353B and 78354A

Measures various body parameters Hewlett-Packard Co., Waltham, MA Manufuscurer:

Problem

Potential for all patient alarms to be Description:

indefinitely suspended

Cause: Software error (D5)

Health consequences: No deaths or injuries reported

Recall Description

Date: 04/22/86

Recall class: ΙI Quantity recalled (units): 4061 Who notified FDA of recall?:

When FDA learned of recall: MDR report?: No 26296 FDA control number:

Case number: 16

Product Identification

Description: Intraocular lens accessories (cannula)

Device class:

Medical specialty: Ophthalmology

Brand: Bailey Lens Shooter/Cannula

Facilitates the implantation of intraocular Use:

lenses

Manufacturer: Pacific Device, Inc., San Diego, CA

Problem

Rust on the exterior, and the tip of the shaft Description:

could dislodge inside the eye

The stainless steel selected for the cannula Cause: was not corrosion resistant (D2)

No deaths or injuries reported Health consequences:

Recall Description

01/21/86 Date:

Recall class: ΙI Quantity recalled (units): 441 Who not fied FDA of recall?: * When FDA learned of recall:

MDR report?: No Z4106 FDA control number:

Case number: 17

Product Identification

Description: Device class:

Medical specialty: Ophthalmology

Brand: Surgidev Slyte 63 Anterior Chamber Intraocular

Intraocular lens

Lens

Use: Replaces lens of human eye Manufacturer: Surgidev Corp., Goleta, CA

Problem

Description: High occurrence of postoperative hyphemia

Cause: Design; could also be operative technique (D1)

Health consequences Patient injury

Recall Description

Date: 03/12/86 Recall class: TI

Quantity recalled (units): Who notified FDA of recall?: Firm

When FDA learned of recall: Before recall MDR report?:

No FDA control number:

26016

Case number: 18

Product Identification

Description: Chromic surgical suture

Device class:

Medical specialty: General and plastic surgery Brand: Soft Gut (Cat Gut) Suture

Used in closing wounds in humans and animals Use: Manufacturer: Davis and Geck, American Cyanamid, Danbury, CT

Problem

Untying of knots caused wound separation Description: Cause: Specific reason for knot insecurity not

identified, probably a material selection

problem (D2)

Patient injury Health consequences:

Recall Description

Date: 08/13/86

Recall class: ΙI Quantity recalled (units): 97 cartons Who notified FDA of recall?: FDA inspection When FDA learned of recall: After recall

MDR report?: Yes

FDA control number: 20077

Case number: 19

Product Identification

Description: Implantable bone growth stimulator

Device class: Medical specialty: Orthopedics Brand: Ostrogen

Use: Stimulates bone growth

Manufacturer: BGS Medical Corp., Milwaukee, WI

Problem

Description: The plastic trays in which the products are

wrapped have high electrostatic potential and may cause stimulators to fail by stressing the integrated circuits

Cause: Packaging of product caused electrical

overstress; problem located in the wash and

pack process (D7)

Health consequences: No deaths or injuries reported

Recall Description

08/14/86 Date:

Recall class:

540 units Quantity recalled (units):

Who notified FDA of recall?: When FDA learned of recall:

MDR report?: Yes FDA control number: 20047

Case number: 20

Product Identification

Description: Prescription daily and extended wear contact

lenses

Device class:

Medical specialty: Ophthalmology CSI (Crofilcom) (A) Daily and Extended Wear Brand:

Use: Correction of vision

Manufacturer: Sola-Suntax Ophthalmics, Phoenix, AZ

Problem

Description: Through a computer error, many lenses labeled

with incorrect expiration dates Lack of software validation (D6)

Cause:

Health consequences: No deaths or injuries reported

Recall Description

12/01/86 Date: III Recall class: 3,000

Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall:

FDA control number: 21567

Case number: 21

Product Identification

Description: Electronic memory cartridge for pacemaker

Device class: 3

Medical specialty: Cardiovascular

Brand: Intermedics Pacemaker Program Module,

Electronic Memory

Use: Obtains data from Intermedics programmable

pulse generator

Manufacturer: Intermedics, Inc., Freeport, TX

Problem

Description: "High" lead impedance may be displayed,

instead of the actual measured lead

impedance

Cause: Displayed a "high" lead impedance when used

with Cosmos and Nova pulse generators, for lead impedances over 600 ohms (D5)

Health consequences: No deaths or injuries reported

Recall Description

Date: 09/25/86
Recall class: 111

Quantity recalled (units): 1,099 units Who notified FDA of recall?: Firm

When FDA learned of recall: Before recall

MDR report?: No FDA control number: Z1307

Case number: 22

Product Identification

Description: Automatic/implantable cardioverter

defibrillator^b

Device class:

Medical specialty: Cardiovascular

Brand: AICD Model AIDB or AID-BR

Use: Tests ventricular tachycardia and fibrillation

Manufacturer: Cardiac Pacemakers, St. Paul, MN

Problem

Description: Electrical failure

Cause: Failure in 50 ohm internal resistors manufactured with shorter and smaller

diameter internal wire; may cause failure of internal fuse, totally disabling device (D2)

Health consequences: No deaths or injuries reported

Recall Description

Date: 02/02/87 Recall class: II Quantity recalled (units): 319

Who notified FDA of recall: Firm When FDA learned of recall: Before recall

MDR report?: Yes
FDA control number: Z2307

Case number: 23

Product Identification

Description: Device class: Medical specialty:

Brand: Use:

Manutacturer:

Ophthalmic saline solution

Ophthalmology

Alcon Saline Solution for Sensitive Eyes Rinsing, storing, and disinfecting daily and

extended wear contact lenses

Alcon Laboratories, Inc., Fort Worth, TX

Problem

Description:

Cause:

Product contaminated with toluene and xylene Product contaminated due to absorption of solvent or exposure to vapors (D3) No deaths or injuries reported

Health consequences:

Recall Description

Date: Recall class:

Quantity recalled (units):

219 bottles Who notified FDA of recall?: User

When FDA learned of recall:

Before recall MDR report: FDA control number: 22217

Case number: 24

Product Identification

Description:

Unipolar and Bipolar programmable single

11/21/86

ΙT

Device class:

Medical specialty:

Brand: üse:

Manufacturer:

chamber heart pacemaker

Cardiovascular Teletronics 10 mm Optima-MPT Pacemaker

Regulates cardiac rate and rhythm Teletronics, Inc., Lane Cove, NSW [Foreign]

Problem

Description:

Sudden no-output failure mode caused by "tin whiskers"

Cause:

Growth of "whiskers" from silver or tincopper compounds used in the diode (D2)

Health consequences: No deaths or injuries reported

Recall Description

Date:

Recall class: Quantity recalled (units):

Who notified FDA of recall?: When FDA learned of recall: MDR report?:

FDA control number:

03/19/87

I 3,127

Yes 23457

Case number: 25

Product Identification

Description: Kidney lithotripter electrode

Device class:

Medical specialty: Gastroenterology, urology

Brand: Dornier 700 and 900

Use Provides ultrasonic shockwaves for fragmenting

renal stones

Manufacturer: Dornier Medizintechnik, Germering [Foreign]

Problem

Description: Epoxy that holds locking mechanism to the

electrode may fail, altering focus position

Cause: Age or storage conditions of epoxy (D2)

Health consequences: No deaths or injuries reported

Recall Description

05/22/87 Date: Recall class: ΙI

673 Quantity recalled (units): Who notified FDA of recall?: Firm

When FDA learned of recall: Before recall

MDR report?: Yes FDA control number: Z4777

Case number: 26

Product Identification

Description: Neodynium YAG laser

Device class: Medical specialty: Anesthesiology

Optilase 1000 YAG Laser System Brand:

Used for laser delivery in peripheral vascular Use:

use

Manufacturer: Trimedyne, Inc., Santa Ana, CA

Problem

Description: Noncompliance with performance standard for

laser products

Laser discharged without requiring fiber to be Cause:

in fiber optic part or pressure on toot switch; beam attenuator and safety interlock do not comply with requirements of standard

(D1)

21178

Health consequences: No deaths or injuries reported

Recall Description

Date: 12/09/87 11 Recall class: Quantity recalled (units): 18 units

Who notified FDA of recall?: When FDA learned of recall: No

MDR report?: FDA control number:

Case number: 27

Product Identification

Description: Device class:

: Cardiovascular

Medical specially:
Brand:

Edwards Duromedics Aortic Bileaflet Valve, Model 3160

Use:

Replaces natural or prostnetic heart valve

Manufacturer:

Hemex Scientific, Austin, TX

Replacement heart valve

Problem

Description: Cause: Defective valves due to leaflet escape
Firm has been unable to determine why the

valves are failing (D1)

Health consequences: Patient death

Recall Description

Date: 06/!3/88
Recall class: 1
Quantity recalled (units): 26,000
Who notified FDA of recall: *
When FDA learned of recall: *
MDR report?: Yes

FDA control number: 24648

Case number: 28

Product Identification

Description: Kidney lithetripter Device class: 3

Medical specialty: Gastroenterology, urology Brand: Dornier Kidney Lithotripter

Use: Disintegrates kidney stones with shockwaves

through a water medium

Manufacturer: Dornier Medizintecknik GMBH, Germering

[Foreign]

Problem

Description: Patient burns

Cause: Product design allows patient contact with

cushion lamp for extended period of time

(D1)

Health consequences: Patient injury

Recall Description

Date: 06/17/88
Recall class: II
Quantity recalled (units): 10
Who notified FDA of recall: *

When FDA learned of recall: MDR report?:

MDR report?: No FDA control number: 25256

aCause codes in parentheses are explained in table 2.1.

bSome recalls were listed in the FDA data base as being of 'defibrillators" and others as of "defibrillator batteries." Because some of the former also appear to concern battery problems and because there has been controvers, over the accuracy of FDA's descriptions of recalls (see <u>Biomedical Safety and Standards</u>, 19:7 (April 1, 1989), pp. 50-51), we have listed all such recalls as being of "defibrillators." However, this should also be understood to cover cases in which only battery packs or other components were recalled.

Source: FDA recall data tape.

Profiles of Class I Medical Device Recalls 1983-88

Case number: 1

Product Identification

Description: Device class:

Medical specialty: Brand:

Use:

Premarketing approval?: Manufacturer:

Bypass valve (hemodialysis machine)

Gastroenterology, urology

Used in an artificial kidney machine for treatment of patients with renal tailure

No

Extracorporeal, Inc., Pinelia's Park, FL

Problem

Description: Cause:

Valve failed to go into bypass mode Residual magnetism in armature and yoke assembly of valve

Patient injury

09/17/82

3,215 valves

Health consequences: Recall Description

Recall date: Quantity recalled (units): Who notified FDA of recall?:

When FDA learned of recall: MDR report?: FDA control number: U0 123

Case number: 2

Product Identification

Description: Device class:

Medical specialty:

Use:

Premarketing approval?:

Manufacturer:

Anesthesiology

No Ohmeda, Inc., Madison, WI

Carbon dioxide absorber

Problem

Description:

Exhalation port to breathing bag blocked and activation of oxygen flush valve prevented

Disc occluded exhalation valve

Health consequences: Patient death

Recall Description

Recall date: Quantity recalled (units): Who notified FDA of recall?:

When FDA learned of recall: MDR report?:

FDA control number:

04/08/83 74,000 units

During recall No

U1443

*Missing or not clearly indicated on the FDA recall data tape

Product Identification

Description: Intraocular lens Device class:

Medical specialty:

Ophthalmology Brand:

Replaces lens of human eye

Premarketing approval?: Manufacturer: Intermedics Intraocular, Inc., Pasadena, CA

Problem

Description: Nonsterility

Cause: Product sterilized in a case for which

sterilization process had not been validated

Health consequences: No deaths or injuries reported

No

Recall Description

Recall date: 06/07/83 Quantity recalled (units): 980 lenses

Who notified FDA of recall?:

When FDA learned of recall: During recall

MDR report?: No

FDA control number: U1743

Case number:

Product Identification

Description: Replacement heart valve

Device class:

Medical specialty: Cardiovascular

Bjork-Shiley Convexo-Concave Heart Valve Brand: Use: Replaces natural or prosthetic heart valve

Premarketing approval?:

Manufacturer: Shiley, Inc., Irvine, CA

Problem

Description: Strut failure

Cause: Inadequate welding, validation, and stress

testing procedures

Health consequences: Patient death

Recall Description

06/06/83 Recall date: Quantity recalled (units): 5,770 valves

Who notified FDA of recall?: Firm

When FDA learned of recall: During recall

MDR report?:

FDA control number: U1523

Product Identification

Description: Anesthesia machine Device class:

Medical specialty: Anesthesiology Brand: Foregger 710 and 705

Use:

Administers anesthetic agents to induce general anesthesia during surgery

Premarketing approval?:

Manufacturer: Puritan Bennett, Kansas City, MO

Problem

Description: Sticking spool valves, resulting in excessive

or inadequate anesthesia delivery

Cause: In switching from one mode to another, valve

can become partially or fully stuck and not

go into the specified mode

Health consequences: Patient death

Recall Description

Recall date: 07/18/83 Quantity recalled (units): Who notified FDA of recall?: 733 units

When FDA learned of recall: During recall

MDR report?: No FDA control number: U2043

Case number: 6

Product Identification

Description: Catheter

Device class:

Medical specialty: Gastroenterology, urology

Brand:

Use: Provides temporary vascular access for

hemodialysis in acute renal failure

Premarketing approval?: No

Manufacturer: Cobe Labs, Lakewood, CO

Problem

Description: Nonsterility

Cause: Lot released for shipment without undergoing

sterilization

Health consequences: No deaths or injuries reported

Firm

Recall Description

Recall date: 06/24/83

Quantity recalled (units): 840 catheters

Who notified FDA of recall?: When FDA learned of recall:

MDR report?: No

FDA control number: U1813

Product Identification

Description: Replacement aortic valve

Device class:

Medical specialty: Cardiovascular

Brand: Bjork-Shiley Convexo-Concave 60-Degree Cardiac

Valve Prosthesis

Replaces natural or prosthetic heart valve Use:

Premarketing approval?: Yes

Manufacturer: Shiley, Inc., Irvine, CA

Problem

Description: Strut failure

Cause: Inadequate welding, validation, and stress

testing procedures

Health consequences: Patient death

Recall Description

Date: 07/06/83

Recall class:

Quantity recalled (units): 7,400 valves

Who notified FDA of recall?: Firm When FDA learned of recall: MDR report?: No FDA control number: U2183

Case number: 8

Product Identification

Description: Dialysis unit

Device class:

Medical specialty: Gastroenterology, urology

Brand:

Recirculation in kidneys for patients with

kidney fallure

Premarketing approval?:

Extracorporeal, Inc., Pinella's Park, FL Manufacturer:

Problem

Possible miswiring of transformer circuit Description: caused increase in dialysate temperature

Wires transposed leading from transformer to Cause:

circuit board

Health consequences: Patient death

Recall Description

Recall date: 10/30/83 Quantity recalled (units): 96 units Who notified FDA of recall?: User

When FDA learned of recall: During recall No

MDR report?: FDA control number: 20434

Product Identification

Description:

Pacemaker

Device class: Medical specialty:

Cardiovascular

Brand: Gamma Series lithium cupric sulfide cells

Regulates cardiac rate and rhythm Use:

Premarketing approval?: No

Manufacturer: Cordis, Mlami, FL

Problem

Batteries had shorter-than-predicted service Description:

life

Problem cause: Use of unprotected feed-throughs in certain

Codel lithium cupric sulfide cell lots resulted in dendritic growth, depleting

battery due to current drain

Health consequences: Patient injury

Recall Description

Recall date: 12/02/83

Quantity recalled (units): 10,878 pacemakers

Who notified FDA of recall?: Firm

When FDA learned of recall: Before recall

MDR report?: No FDA control number: 20664

Case number: 10

Product Identification

Description: Pediatric crib with security top

Device class:

Medical specialty: Physical medicine

Brand:

Use: Holds pediatric patients

Premarketing approval?: Manufacturer: Midmark, Versailles, OH

Problem

Description: Entrapment of patients

Top incorrectly installed or secured Cause:

Health consequences: Patient death

Recall Description

03/01/84 Recall date:

Quantity recalled (units): 1,000 cribs

Who notified FDA of recall?: User

When FDA learned of recall: Before recall

MDR report?: No

ZU584 FDA control number:

Case number: 11

Product Identification

Description: Q-fever-positive numan serum, 0.5-ml vials

Device class:

Medical specialty: Microbiology

Brand:

Use: In vitro diagnosis of Q fever

Premarketing approval?:

Manufacturer: Centers for Disease Control, Atlanta, GA

Problem

Description: Product did not meet Centers for Disease

Control quality standard

Cause: Instability of reagent

Health consequences: No deaths or injuries reported

Recall Description

Recall date: 01/18/84 Quantity recalled (units): Who notified FDA of recall?: 210 vials

Firm

When FDA learned of recall: During recall

MDR report?: No

FDA control number: 20194

Case number: 12

Product Identification

Description: Pacemaker

Device class:

Medical specialty: Cardiovascular Brand:

Use: Regulates cardiac rate and rhythm Premarketing approval?:

Cardiac Pacemakers, Inc., St. Paul, MN Manufacturer:

Problem

Description: Device could abruptly fail due to shorting of

timing crystal

Cause: Due to an improper case composition, dendrites may grow from the case of the crystal into

the tuning fork, causing a short and resulting in sudden loss of output

Health consequences: No deaths or injuries reported

Recall Description

Recall date: 01/30/84

Quantity recalled (units): Who notified FDA of recall?: Firm

During recall

When FDA learned of recall:

MDR report?: No

FDA control number: 21024

Case number: 13

Product Identification

Description: Pediatric crib Device class:

Medical specialty: General hospital

Brand:

Holds pediatric patients after surgery Use:

Premarketing approval?: No

Cambridge Scientific Industries, Cambridge, MD Manufacturer:

Problem

Description: Risk of entrapment if improperly assembled or

secured

Poor design of crib Cause:

Health consequences: No deaths or injuries reported

Recall Description

Recall date: 06/07/84 Quantity recalled (units): Who notified FDA of recall?: 76 cribs Firm

When FDA learned of recall: Before recall

MDR report?: No

22744 FDA control number:

Case number: 14

Product Identification

Pediatric crib Description: Device class:

Medical specialty: General hospital Brand:

Holds pediatric patients after surgery or lise:

active pediatric patients

No

Premarketing approval?:

Hill-Rom Co., Batesville, IN Manufacturer:

Problem

Entrapment of patients, which resulted in Description:

serious injuries and deaths

Cause:

Design of bed, including assembly instructions, allowed the entrapments

Patient death Health consequences:

Recall Description

05/18/84 Recall date: 213 cribs Quantity recalled (units):

Who notified FDA of recall?: User

Before recall When FDA learned of recall:

MDR report?: No FDA control number:

21944

Product Identification

Description: Apnea monitor Device class: 2 Medical specialty: Anesthesiology

Brand:

Use: Ventilates and monitors infant breathing No

Premarketing approval?:

Manufacturer: Healthdyne, Home Care Products Division,

Marietta, GA

Problem

Description: Low respiration sensitivity alarm did not

function as designed

Static electricity caused damage to electrical Cause:

components and circuitry

Health consequences: Patient death

Recall Description

Recall date: 02/01/84 Quantity recalled (units): 7,000 units Who notified FDA of recall?: FDA inspection When FDA learned of recall: During recall

MDR report?:

No FDA control number: Z3214

Case number: 16

Product Identification

Description: Anesthesia machine (T-handle)

Device class:

Medical specialty: Anesthesiology

Brand: Foregger Model 705 and 710 Selects various vaporizer modes

Premarketing approval?: No

Puritan-Bennett Corp., Overland Park, KS Manufacturer:

Problem

Description: Certain vaporizer turrets developed a loose

> "T" handle, resulting in inaccurate vaporization of liquid anesthesia agents Epoxy bond may tracture, permitting handle to

Cause: wobble and resulting in an intermittent by-

pass leak within the turret manifold

Health consequences: No deaths or injuries reported

Recall Description

Recall date: 10/08/84 Quantity recalled (units): 73 units Who notified FDA of recall?: User When FDA learned of recall: Before recall

MDR report?: No FDA control number: 20445

Product Identification

Description: Device class:

Medical specialty: Brand:

Use:

Premarketing approval?: Manufacturer:

vitrectomy No Cooper Vision, Inc., Irvine, CA

C V Fragmatome Aspiration Tubing

Silicone tubing

Anesthesiology

Problem

Description:

Stiff tubing that may prevent suction cutoft

Cause:

Vendor provided defective raw materials that did not meet the specifications, resulting in a defective finished product

Used in anterior segment surgery and posterior

Health consequences: Patient injury

Recall Description

Recall date: 12/19/84 Quantity recalled (units): Who notified FDA of recall?: 674 units FDA Inspection When FDA learned of recall: During recall

MDR report?: No FDA control number: 21545

Case number: 18

Product Identification

Description: Device class: Medical specialty:

Brand: Use:

Anesthesiology

Regulates positive pressure breathing in both home and hospital use

Premarketing approval?:

Manufacturer:

No

Life Products, Inc., Boulder, CO

Positive pressure volume ventilator

Problem

Description:

Erratic or stopped cycling, sticking power switch and alarm, etc.

Cause: Circuitry problems and deficiencies;

components did not perform reliably although they met original design specifications

Health consequences: No deaths or injuries reported

Recall Description

Recall date:

Quantity recalled (units): Who notified FDA of recall?:

When FDA learned of recall:

MDR report?: FDA control number: 06/20/84 252 ventilators

Firm During recall

No 23354

Product Identification

Description:

Device class: Medical specialty:

Brand:

Use:

Premarketing approval?:

Manufacturer:

Calibrated vaporizers

Anesthesiology

Used in gas-dispensing circuit of anesthesia

machine, to vaporize anesthetic

Ohmeda, Madison, WI

Problem

Cause:

Description:

compensation mechanism

Thrust pin loosened due to shock,

impact, or excessive vibration of the

Failure of thrust pin in the temperature

aporizer

11/14/84

Yes

20675

Undetermined

FDA inspection

Before recall

Health consequences: Patient death

Recall Description

Recall date:

Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall:

MDR report?: FDA control number:

Oxygen flush valves

Case number: 20

Product Identification

Description:

Device class: Medical specialty:

Brand:

Use:

Anesthesiology

Component of anesthesia machine that flushes breathing circuits with oxygen No

Premarketing approval?:

Manufacturer:

Puritan Bennett Corp., Overland, KS

Problem

Description:

E-clip used in valve distorts internal diaphragm, causing intermittent leak of

oxygen

Clip added to valve in 1982; after 1.5 years, Cause:

clip began distorting diaphragm No deaths or injuries reported

Health consequences:

Recall Description

Recall date: Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall:

90 valves User Before recall

09/19/84

No

MDR report?: FDA control number:

20335

Product Identification

Description: Device class:

Medical specialty:

Brand:

Use:

Premarketing approval?:

Manufacturer:

Apnea monitor/pradycardia detector

General hospital

Monitors respiration and heart rate in

infants

NO

Clinical Data, Inc., Boston, MA

Problem

Description:

Alarms may not sound if intant breathing or

heart rate slows or stops

Cause:

Sensitivity to electrostatic discharge of integrated circuits (through metal set screws on knobs on detector panel)

Health consequences:

No deaths or injuries reported

Recall Description

Recall date:

Quantity recalled (units): 2,210 monitors Who notified FDA of recall?: FDA inspection When FDA learned of recall:

MDR report?: FDA control number: Betore recall No

22585

02/08/85

Case number: 22

Product Identification

Description: Device class: Medical specialty:

Brand:

Use: Premarketing approval?:

Manufacturer:

Defibrillatora

Cardiovascular

Power source for cardiac defibrillators

General Electric Co., Battery Business, Gainesville, FL

Problem

Cause:

Description:

Abnormally rapid loss of discharge capacity after charging and removal from charger Possible that cobalt was inadvertently incorporated into batteries during

Health consequences:

manufacture Patient injury

Recall Description

Recall date:

Quantity recalled (units): Who notified FDA of recall?: FDA inspection When FDA learned of recall: MDR report?:

FDA control number:

03/08/85

3,453 batteries Before recall

No 22715

Product Identification

Description: Device class:

Medical specialty:

Brand:

Premarketing approval?:

Manufacturer:

Defibrillatora

Cardiovascular

Power source for Pioneer Pulsar 4 cardiac

detibrillators

No

General Electric Co., Gainesville, FL

Problem

Description:

Batteries lost a substantial portion of their charge 1 hour to 4 days after disconnection from the battery charger

Cause:

Possible that cobalt was inadvertently incorporated into batteries during manufacture

Health consequences: No deaths or injuries reported

Recall Description

Recall date:

02/28/85 Quantity recalled (units): 60 batteries Who notified FDA of recall?: FDA inspection When FDA learned of recall: Before recall No

MDR report?: FDA control number:

Z3475

Case number: 24

Product Identification

Description:

Device class:

Medical specialty:

Brand:

Use:

Premarketing approval?:

Regulates cardiac rate and rhythm

Cordis, Miami, Fl

Cardiovascular

Problem |

Description:

Manufacturer:

Cause:

Potential for sudden loss of output Batteries give off dioxolane vapor

(electrolyte); boards absorbed vapor and expanded, breaking unfilled open-plated

holes

Pacemaker

Health consequences:

Patient injury

Recall Description

Recall date:

04/19/85

Quantity recalled (units): Who notified FDA of recall?:

28,931 pacemakers Competitor Before recall

When FDA learned of recall: MDR report?:

NO

FDA control number:

23415

Case number: 25

Product Identification

Description: Defibrillator^a
Device class: 2
Medical specialty: Cardiovascular

Brand:

Use: Power source for cardiac defibrillators

Premarketing approval?: No

Manufacturer: General Electric Co., Gainesville, FL

Problem

Description: Batteries were contaminated with cobalt that

could cause battery and defibriliator

failure

Cause: Cobalt was introduced unknowingly onto the

negative plate during the plate impregnation

process

Health consequences: Patient injury

Recall Description

Recall date: 02/15/85

Quantity recalled (units): 8,200 batteries

Who notified FDA of recali?: Firm

When FDA learned of recall: Before recall

MDR report?: Yes FDA control number: 23025

Case number: 26

Product Identification

Description: Hemodialysis delivery system and monitor

Device class:

Medical specialty: Gastroenterology, urology
Brand: *

brand

Premarketing approval?: *

Manufacturer: Drake Willock Division, CD Medical Co.,

Portland, OR

Problem

Description:

Cause:

Sticking or nonfunctional bypass valves Use of stainless steel in valve that was susceptible to corrosion; during normal

operation, valve's plunger and plunger guide

surface are wetted by dialysate

Health consequences: Patient injury

B = 33 B

Recall Description

Recall date:

02/11/85 ts): 12,300 units

Quantity recalled (units): 12,30 Who notified FDA of recall?: Firm

When FDA learned of recall: During recall

MDR report?:

FDA control number: 22545

Case number: 27

Product Identification

Description: Device class:

Medical specialty:

Brand:

Use:

Premarketing approval?:

Manufacturer:

Defibrillatora

Cardiovascular

General Electric Co., Gainesville, FL

Power source for cardiac defibrillators

Problem

Description:

Cause:

Batteries can lose part of their charge after disconnection from the battery charger Cobalt introduced unknowingly onto negative

plate during the plate impregnation process

in battery manufacture No deaths or injuries reported

Health consequences:

Recall Description

Recall date: 06/24/85 Quantity recalled (units): 130 batteries

Who notified FDA of recall?: Firm

When FDA learned of recall: Before recall

MDR report?: Yes FDA control number: Z3055

Case number: 28

Product Identification

Description: Device class: Medical specialty:

Brand:

Use:

Cardiovascular

Hospital's emergency room or operating room cardiac stimulator

Premarketing approval?:

Manufacturer:

Yes

Defibrillatora

General Electric Co., Battery Business,

Gainesville, FL

Problem

Cause:

Description:

Batteries fail at a high rate; abnormally rapid loss of discharge capacity after

being charged

Health consequences:

Reportedly contaminated with cobalt, an unapproved material, during production

No deaths or injuries reported

Recall Description

Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall:

MDR report?: FDA control number:

03/19/85 152 batteries FDA inspection Before recall

No 22855

Case number: 29

Product Identification

Description:

Device class:

Medical specialty:

Brand:

Use: Premarketing approval?:

Manufacturer:

Vaporizer

Anesthesiology Ohmeda (for halothane and ethranes)

Vaporizes anesthesia gas

Yes

Primary Medical Products, Los Angeles, CA

Problem

Description:

Misbranding: conversion for use with

anesthetic agents other than those for which

vaporizer was designed

Cause:

Device converted from one type of vaporizer to another without a 510(k) or PMA application

Health consequences: No deaths or injuries reported

Recall Description

Recall date:

07/16/85 Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall:

MDR report?: FDA control number:

23 units FDA inspection Before recall

No Z1696

Case number: 30

Product Identification

Description: Device class:

Medical specialty: Brand:

Premarketing approval?:

Manufacturer:

Defibrillatora

Cardiovascular

Saft "ED" Electrodeposited Nickel-Cadmium Battery Cell

Alternate power source for defibrillators

Saft America, Inc., Valdosta, GA

Problem

Description: Cause:

Premature nickel-cadmium battery failures Short circuits due to nickel screen electrode edges protruding over electrode separator and masking contact with other electrodes

No deaths or injuries reported

Health consequences: Recall Description

Recall date:

Quantity recalled (units): Who notified FDA of recall?:

When FDA learned of recall: MDR report?:

FDA control number:

03/29/85

3,145 batteries

User

Before recall

NO

Z4655

Product Identification

Description: Dialysate delivery system

Device class: 2

Medical specialty: Gastroenterology, urology

Brand:

Use: Patient dialysis

Premarketing approval?: No

Manufacturer: Drake Willock Division, C. D. Medical,

Portland, OR

Problem

Description: Problems with bypass mode, blood pump,

concentrate rods, and flow rate indicator
Cause: Gate B on the integrated circuit was not

performing as expected, allowing the bypass

valve to remain open during alarm conditions

Health consequences: No deaths or injuries reported

Recall Description

Recall date: 04/30/85

Quantity recalled (units): 535 units

Who notified FDA of recall?: Firm

When FDA learned of recall: During recall MDR report?: Yes

FDA control number: Z4285

TDA CONCLOI NUMBER: Z4205

Case number: 32

Product Identification

Description: Portable positive pressure respirator

Device class:

Medical specialty: Anesthesiology

Brand: Volume Ventilators Model LP-3, LP-42, LP-5 Use: Ventilates patients who need complete or

partial breathing assistance

Premarketing approval?: No

Manufacturer: Life Products, Inc., Boulder, CO

Problem

Description: Motor and alarm malfunction, circuit detects,

circuit boards fall out

Cause: Numerous good manufacturing practices violations in handling of components,

manufacturing procedures, and testing

Health consequences: Patient death

Recall Description

Recall date: 10/07/85

Quantity recalled (units): 5,304 respirators Who notified FDA of recall?: FDA inspection When FDA learned of recall: Before recall

When FDA learned of recall: Betor MDR report?: Yes FDA control number: 21966

Product Identification

Description:

Device class: Medical specialty:

Brand:

Manufacturer:

Premarketing approval?:

Replacement heart valve

Cardiovascular

Bjork-Shiley Cardiac Valve Prosthesis 600 (Mitral and Aortic)

Replaces natural or prosthetic heart valve

Yes

Shiley, Inc., Irvine, CA

Problem

Description:

Cause:

Strut of the valves may tracture

Firm developed larger valves, having had minimal failure with small valves; strut

failures began shortly after

Health consequences: Patient death

Recall Description

Date:

Recall class: Quantity recalled (units):

2,752 valves

F1 rm

Who notified FDA of recall?: When FDA learned of recall:

Before recall

10/14/85

MDR report?:

No Z1536

FDA control num er:

Case number: 34

Product Identification

Description:

Cardiac pulse generator

Device class:

Medical specialty:

Cardiovascular

Brand:

Programmalith III

Use:

Regulates cardiac rate and rhythm

Premarketing approval?:

Manufacturer: Pacesetter Systems, Inc., Sylmar, CA

Problem

Description:

Loss of function and telemetry due to temperature sensitivity of circuits

Cause:

Combination of resistance and amplifier gain in oscillator creates abnormal sensitivity

to temperature

Health consequences:

Patient injury

Recall Description

Date:

09/04/85

Recall class:

Quantity recalled (units): Who notified FDA of recall?:

690 pacemakers Firm

When FDA learned of recall:

Before recall

MDR report?:

No

FDA control number:

21246

Product Identification

Description:

Device class:

Medical specialty:

Brand: Use:

Premarketing approval?:

Manufacturer.

Anesthesiology

Infant ventilator

Bear Cub Infant Ventilator Model BP 2001 Provides respiratory support to intants

No

07/17/85

Firm

21306

No

390 ventilators

During recall

Defibrillatora

Cardiovascular

Bear Medical Systems, Inc., Riverside, CA

Problem

Description:

Cause:

Health consequences:

Sudden increase in positive-end expiratory pressure caused by a component failure

Failure of the variable oritice valve; can delay exhalation enough to cause an increase

in positive-end expiratory pressure

No deaths or injuries reported

Recall Description

Recall date:

Quantity recalled (units):

Who notified FDA of recall?:

When FDA learned of recall:

MDR report?:

FDA control number:

Case number: 36

Product Identification

Description: Device class:

Medical specialty:

Brand:

Use:

Premarketing approval?:

Manufacturer:

Problem

Cause:

Description:

charger A defect in the nickel-cadmium battery

provided by General Electric may cause the battery to fail

Power source for cardiac defibrillators

Abnormally rapid loss of discharge capacity atter being charged and removed from

Battery $Sp \epsilon$ lalties, Cookville, TN

No deaths or injuries reported

General Electric (Batteries)

Recall Description

Health consequences:

Recall date:

Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall: MDR report?:

FDA control number:

No Z5805

11/18/85

Product Identification

Description: Device class:

Medical specialty:

Brand:

Use: Premarketing approval?:

Manufacturer:

Sportcide-disinfectant for hemodialyzers $\boldsymbol{2}$

Gastroenterology, urology Renew-D Disintectant

Disinfects reused hemodialysis equipment

No Algida Corporation Nortalk

Alcide Corporation, Norwalk, CT

Problem

Description:

Gram-negative organisms were found in dialyzer after use of the disinfectant; patients experienced pyrogen-like reactions and

bacteremias

Cause:

The product as originally designed was not

effective for its intended use

Health consequences: Patient injury

Recall Description

Recall date:

Recall date: 06/09/86
Quantity recalled (units): 4,000 cases
Who notified FDA of recall?: Firm

When FDA learned of recall: During recall

MDR report?: Yes FDA control number: 26066

Cardiovascular

Case number: 38

Product Identification

Description:

Unipolar and Bipolar programmable single

chamber heart pacemaker

Device class:
Medical specialty:

Medical specialty: Brand:

Use: R
Premarketing approval?: Y

Manufacturer:

Teletronics 10 mm Optima-MPT Pacemaker

Regulates cardiac rate and rhythm

Yes

Teletronics, Inc., Lane Cove, NSW (Foreign)

Problem

Description:

Sudden no-output failure mode caused by "tin
whiskers"

Cause: Growth of

Growth of "whiskers" from silver or tincopper compounds used in the diode

Health consequences: No deaths or injuries reported

Recall Description

Date:
Recall class:

Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall: MDR report?:

FDA control number:

*
*
Yes
23457

3,727

03/19/87

Case number: 39

Product Identification

Description: Medical linear accelerator

Device class: 2

Medical specialty: Radiology

Brand: Therac-25 Linear Accelerator
Use: Used in clinical (cancer) radiotherapy

Premarketing approval?: No

Manufacturer: Atomic Energy of Canada, Ltd., Ontario

Problem

Description: Software defects could cause massive, fatal

radiation overdoses

Cause: Two software defects that may cause massive

Health consequences: radiation Patient death

Recall Description

Recall date: 06/03/87

Quantity recalled (units): 5 accelerators

Who notified FDA of recall: *
When FDA learned of recall: *
MDR report?: No

FDA control number: Z3827

Case number: 40

Product Identification

Description: Implantable pacing leads

Device class:

Medical specialty: Cardiovascular

Brand: "Lifeline" Bipolar, Coaxial Implantable

Leads

Use: Used with internal pacemakers for long-term

pacing of the heart

Premarketing approval?: No

Manufacturer: Intermedics, Inc., Freeport, TX

Problem

Description: Increased failure manifested by over- and

under-sensing, loss, and failure to stimulate
Cause: Polyurethane insulation for the inner coil
developed a localized weakness which failed

(cracked) and resulted in intermittent contact between the inner and outer coils

Health consequences: Patient injury

Recall Description

Recall date: 07/20/87

Quantity recalled (units): 2,197 leads

Who notified FDA of recall?: When FDA learned of recall:

MDR report?: No FDA control number: 25337

Product Identification

Description: Blood oxygenator with integral filter

Device class:

Medical specialty: Cardiovascular

Brand: CML-2 Membrane Oxygenator

Use: Blood gas exchange during cardiac surgical

procedures

Premarketing approval?: No

Manufacturer: Cobe Labs, Lakewood, CO

Problem

Description: Outlet connector of venous reservoir could be

loosened, allowing air and fluid leakage

Cause: Leak appears to occur in outlet connector

at screw threads

Health consequences: Patient death

Recall Description

Recall date: 08/19/87

Quantity recalled (units): *
Who notified FDA of recall?: Firm

When FDA learned of recall: During recall

MDR report?: Yes
FDA control number: 25867

Case number: 42

Product Identification

Description: Respirator, neonatal ventilator

Device class: 2

Medical specialty: Anesthesiology

Brand: Healthdyne Model 105, Type 3 Intant

Ventilator

Use: Provides respiratory support to infants in

hospital neonatal intensive care units

Premarketing approval?: No

Manufacturer: Healthdyne, Inc., Marietta, GA

Problem

Description: Stopped functioning during use and had

burnt odor; some developed internal

1110

Cause: Reversed positioning of a capacitor on the

electronic version of pressure alarm

Health consequences: No deaths or injuries reported

Recall Description

Recall date: 05/07/87

Quantity recalled (units): 65 respirators

Who notified FDA of recall?: Firm

When FDA learned of recall: During recall

MDR report?: Yes
FDA control number: 25877

Product Identification

Description:

Pacemaker

Device class:

Medical specialty:

Cardiovascular CPI/Ultra Unipolar and Bipolar

Brand:

Regulates cardiac rate and rhythm

Premarketing approval?:

Yes

Manufacturer:

Cardiac Pacemakers, St. Paul, MN

Problem

Description:

High pacing rate, no output, no sensing, loss of interrogation and telemetry capacity

Cause:

Gold migration through dielectric paste from one circuit pathway to another, causing short; detective vendor lot of dielectric

paste

Health consequences:

Patient death

Recall Description

Recall date:

10/27/87

Quantity recalled (units):

1,911 pacemakers

Who notified FDA of recall?:

Firm Before recall

When FDA learned of recall: MDR report?:

Yes

FDA control number:

Case number: 44

20528

Product Identification

Description:

Sorbent regenerated dialysate delivery system

for hemodialysis

Device class:

Medical specialty:

Gastroenterology, urology "Redy" 2000 and "Dialert"

Brand:

Use:

Treatment of acute and chronic renal failure

Premarketing approval?:

No

Manufacturer:

Organon Teknika Corp., Oklahoma City, OK

Problem

Description:

May infuse unsafe levels of potassium and/or

calcium into dialysate

Cause:

Intermittent sensing by electrode sensor, sending incorrect voltage to infusate pump

Health consequences:

No deaths or injuries reported

Recall Description

02/29/88 304 units

Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall:

Firm Before recall

MDR report?:

No

FDA control number:

2 3 4 7 8

Product Identification

Description: Device class:

Medical specialty: Brand:

Use:

Premarketing approval? Manufacturer:

Anesthesiology

Volume ventilator

"Bear 1" Adult Volume Ventilator

Delivers air or oxygen to patients in need of

respiratory support

No

Bear Medical Systems, Inc., Riverside, CA

Problem

Description:

Reports of fire that may be due to defective main solenoid

Cause:

Rubber in piston valve of the solenoid comes loose, resulting in metal-to-metal contact; sparks can ignite oxygen

Health consequences:

Patient death

Recall Description

03/23/88 Quantity recalled (units): 1,467 Who notified FDA of recall?: F1 rm When FDA learned of recall: During recall

MDR report?: Yes FDA control number: 24938

#**===**

Case number: 46

Product Identification

Description: Respiratory monitor Device class: Medical specialty:

Brand:

Anesthesiology Apnea Monitor 9200, Respiratory/Heart Rate

Monitors the heart rate and respiration of infants who lun the risk of aphea

Premarketing approval?

Manufacturer:

Monitor

Aquitron Medical, Inc., Minneapolis, MN

Problem

Use:

Description: Cause:

Monitor alarm may tail

Audible alarm was found to have ten percent failure rate when tested at firm

Health consequences: Patient injury

Recall Description

Quantity recalled (units): Who notified FDA of recall?: firm

When FDA learned of recall: MDR report?:

FDA control number:

03/12/88 4,963

During recall Yes

23548

Case number:

Product Identification

Description: Device class:

Medical specialty:

Brand:

Premarketing approval?:

Manufacturer:

Replacement heart valve

Cardiovascular

Edwards Duromedics Aortic Bileaflet Valve,

Model 3160

Replaces natural or prosthetic heart valve

Yes

06/13/88

26,000

Yes

Hemex Scientific, Austin, TX

Problem

Description:

Cause:

Defective valves due to leaflet escape Firm has been unable to determine why the

valves are failing Patient death

Health consequences:

Recall Description

Date:

Recall class: Quantity recalled (units):

Who notified FDA of recall?: When FDA learned of recall: MDR report?:

FDA control number:

24648

Case number: 48

Product Identification

Description:

Device class:

Medical specialty:

Brand:

Use:

Premarketing approval?:

Manufacturer:

Replacement heart valve

Cardiovascular

Medtronic Hall D-16 Prosthetic Heart Valve Replaces natural or prosthetic heart valve

No

Carbomedics, Inc., Austin, TX

Problem

Description:

Mechanical failure resulting from disk

fracture

Cause:

Tension bending force when disc inserted in housing and impact on disc when it strikes

housing seat top Patient death

Health consequences:

Recall Description

Date:

Quantity recalled (units): Who notified FDA of recall?: When FDA learned of recall:

MDk report?:

FDA control number:

07/19/88 317 valves

No 25908

asome recalls were listed in the FDA data base as being of "defibrillators" and others as of "defibrillator batteries." Because some of the former also appear to concern battery problems and because there has been controversy over the accuracy of FDA's descriptions of recalls (see Blomedical Safety and Standards, 19:7 (April 1, 1989) pp. 50-51), we have listed all such class I recalls as being of "defibrillators." However, this classification should be understood to cover only those cases in which battery packs or other components were recalled.

Source: FDA recall data tape.

Major Contributors to This Report

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